EXHIBIT C

GENERAL REPORT OF E. STANTON (STAN) SHOEMAKER, M.D. REGARDING GYNEMESH PS, PROLIFT, PROLIFT +M AND PROSIMA

The following is my general report regarding Gynemesh PS, Prolift, Prolift +M and Prosima. My report, including the opinions expressed, is based on my education, training, knowledge experience, discussions with colleagues, review of medical literature, attendance at medical meetings, review of medical records and deposition testimony specific to this case, and is based on information I currently have reviewed, information cited in this report, and/or have available to me, as set forth in Exhibit A to this report. Inasmuch as I regularly review medical information, attend and/or participate in medical meetings and consultations with my colleagues as part of my continuing medical education and experience, I reserve the right to add to or modify the opinions set forth in this report. To the extent I receive additional information relevant to my opinions prior to the trial of this case, I reserve the right to modify or add to the opinions set forth below. All of my opinions expressed in this report are held to a reasonable degree of medical and scientific certainty.

I. Background, Training and Experience

I am a board-certified obstetrician-gynecologist practicing in Corpus Christi, Texas. After receiving my undergraduate degree from the University of Texas, I received my medical degree (M.D.) from the University of Texas Medical Branch

in Galveston, Texas in 1973. Thereafter, I did my internship and my residency training at Parkland Hospital in Dallas Texas. I am board-certified in obstetrics and gynecology. Having always been interested in learning and providing to my patients effective, safe and innovative medical treatments and techniques, I was one of the first physicians in Texas to perform laparoscopic surgery for the treatment of gynecologic maladies, including hysterectomies. My practice includes specialized treatment of obstetrics, gynecology, infertility, abdominal laparoscopic surgery, pelvic floor reconstruction, urinary incontinence and family planning. Because of my specialty, I am often referred such surgery, particularly surgery to treat complicated gynecologic maladies, by my colleagues. Similarly, because of my expertise and specialized knowledge and experience, I am often asked to instruct other obstetrician-gynecologists in the surgical treatment of numerous gynecologic maladies. In fact, I have served as a speaker and preceptor for physicians at Ethicon sponsored training sessions. In those training sessions, I have not only demonstrated the proper way to implant Ethicon's various devices, but I have also discussed with them the information contained in their mesh product IFU's and professional education materials. I can therefore attest to the type information discussed at such sessions and relative knowledge of the physicians attending those sessions as to risks and complications not only associated with pelvic mesh, but also other surgeries that address and treat pelvic

floor disorders and SUI. My education and training is set forth in my curriculum vitae attached to this report as Exhibit B.

Having trained from 1973 through 1977 and been in private practice since that time specializing in treatment of pelvic floor disorders and incontinence, I am aware of, and can testify about, the various surgical and non-surgical treatments for such disorders during that period. During my residency, I received extensive training in female pelvic medicine and reconstructive surgery, and thus am familiar and can attest to how physicians are trained and what information is provided during such training. Moreover, because of my continuing medical education, review of medical literature, discussions with colleagues, attendance and participation in medical meetings and teaching other physicians, I am familiar with how this specialized area of medicine is practiced, how physicians obtain information that they rely on in performing surgical procedures, and the manner in which they apprise themselves of and keep up with advances in medicine relevant to the practice of gynecologic medicine. I have seen and experienced and thus can testify to the various revolutionary medical and scientific innovations in this area of medicine which have improved the medical options available to treat women and the quality of life available to them through such innovations.

I have substantial experience with surgical procedures to treat pelvic floor disorders, including pelvic organ prolapse (POP) and stress urinary incontinence

(SUI). I have prescribed both non-surgical treatments including physical therapy, use of pessaries and behavior modification. I have performed in excess of 1500 various surgical procedures to treat POP and SUI, including site specific defect repairs, native tissue repair, biologic grafts, in addition to synthetic grafts. I have treated in excess of 500 patients with POP. Specific to the treatment of SUI, I have utilized various non-surgical treatments including prescription antibiotics to treat urinary tract infections (UTI's) and anticholinergic medications, pelvic floor exercises, sacral nerve stimulation (INTERSTIM)], as well as surgical procedures, including anterior colporrhaphy, Marshall-Marchetti-Krantz (MMK) , the Burch procedure, pubo-vaginal sling procedures using autologous, cadaver and graft materials, and mid-urethral sling procedures utilizing synthetic mesh, the latter of which I consider the gold-standard and current standard of care for surgically treating stress urinary incontinence. Consequently, as a result of my experience, as well as my continuing review of the medical literature, professional society publications, discussions with colleagues and attendance at medical meetings, I can provide testimony about the relative risks and benefits of such procedures, the relative efficacy of such procedures, potential complications of such procedures, how patients respond to such treatments, and the relative satisfaction patients have with their respective treatments.

I am also knowledgeable about, and can therefore attest to, the development of the surgical procedures to treat POP and SUI and how they evolved over time including options available both prior to and after the availability of polypropylene mesh to treat pelvic floor disorders. The procedures utilizing polypropylene mesh, by and large, were created or developed by physicians seeking better, more effective treatments to improve the surgical outcomes in and the quality of life of their patients. Because I have been trained to perform the procedures referenced above, I understand the relative benefits and risks/potential complications associated with each, and how to avoid such complications, if possible, and how best to approach resolution of complications when they do occur.

I have implanted various manufacturers' synthetic mesh products which all have different surgical approaches. My preferred choice for surgically treating POP utilized the various Ethicon products, including Prolift, Prolift +M and Prosima. As a result, I performed hundreds of procedures utilizing the Prolift line of products for treatment of POP. I have also utilized Gynemesh PS™ in treating POP. My preferred choice for treating SUI was and continues to be the slings manufactured by Ethicon inasmuch as I believe them to be the safest and most effective products for surgically treating SUI. I have implanted hundreds of TVT and TVT-Exact products when a retropubic approach is appropriate. Similarly I have performed hundreds of procedures utilizing the TVT-O and TVT-Abbrevo

devices when a transobturator approach has been indicated. Importantly, I have implanted Ethicon's mesh products that employed laser-cut mesh as well as mechanically cut mesh. I never saw any clinical difference between the mechanically cut and laser cut mesh. More specifically, in my experience, there was no difference between the two types of mesh employed in the rates of erosion/exposure/extrusion and dyspareunia in my patients.

It is my opinion that mid-urethral slings are currently considered to be the gold-standard for the treatment of SUI, an opinion which is supported by published literature, as well as the meta-analyses, systematic reviews, published position statements and practice guidelines of numerous organizations specializing in treatment of urological and gynecological treatments, including AUGS, AUA, SUFU, IUGA, AAGL, EAU, NICE and ACOG. I consider these organizations to be highly regarded and respected in my specialized field of practice. I often refer to and rely upon peer-reviewed publications produced by these organizations and their members in forming treatment plans for my patients, as do many of my colleagues, as such publications and papers are often cited as reliable sources for current medical thought and treatment guidelines.

In addition to utilizing the Ethicon products mentioned above, I have also managed complications associated with pelvic mesh procedures, more often than not involving products manufactured by other device manufacturers. I can,

therefore, testify regarding the contributing causes and appropriate treatments for such complications.,

II. Consulting Fees and Testimonial History

My fee for work in this matter is $400 per hour for review and deposition preparation; $700 per hour for time in deposition and for trial preparation; and $5000 per day in trial.

III. Materials Reviewed in Compiling this Report

In addition to the materials previously referenced in this report which serve as the basis for my opinions in this case, I have reviewed the IFUs and Surgical Technique Guide for Ethicon's various mesh devices, as well as Surgeon's Resource Monographs, Professional Education slides, DVD's, animations and surgical videos, Patient Brochures, and other professional education materials relating to Ethicon's mesh devices, including the devices specifically at issue in this case.

This report contains my opinions in this case as of the date of this report. My conclusions and opinions are based on the case-specific materials made available to me as set forth in Exhibit A, the educational materials routinely provided by Ethicon, including those made available for physicians and patients,

and evidence-based information which is available in the customary practice of female pelvic medicine and reconstructive surgery.

IV. Pelvic Floor Disorders

A. Pelvic Organ Prolapse - Background

Pelvic organ prolapse (POP) and urinary incontinence are common conditions which have long-affected many women as they age and bare children. POP occurs when a pelvic organs, such as the bladder, rectum, lower intestines, and/or uterus, drops (prolapses) from its normal place in the lower abdomen or pelvic area and pushes against the walls of the vagina causing the vaginal wall to bulge. This can happen when the muscles and fascia that hold the pelvic organs in place weaken or stretch as the result of aging, childbirth, surgery, and genetic conditions that may cause tissue deterioration. While aging and vaginal childbirth are major risk factors for the development of pelvic organ prolapse, there are many potential contributing factors, including chronic heavy lifting or straining, smoking, obesity, metabolic disorders such as diabetes, loss of muscle tone, estrogen loss associated with menopause, family history, genetics, pelvic trauma or previous surgery, chronic constipation, chronic cough, and connective tissue disorders.

It has been reported that pelvic organ prolapse affects 50% of all parous women. This already overwhelming problem is expected to increase in significance as patients age.

POP significantly affects a woman's quality of life. Women with prolapse may suffer from numerous maladies as a result of a prolapse, including vaginal discomfort, vaginal ulceration and odorous discharge, voiding difficulties and recurrent urinary tract infections, difficulty with bowel movements, as well as sexual dysfunction. The sexual dysfunction can be due not only to pain or discomfort from the prolapse itself, but also due to negative body image and embarrassment about the condition. Conditions such as overactive bladder and resulting incontinence can occur when a prolapse is present, but may also be independent of the prolapse itself.

While an initial POP presentation is a common, but significant, malady in the practice of gynecology, this problem is made worse by the fact that many initial repairs of POP require subsequent, repeat surgery due to prolapse recurrence. Published data suggest that the lifetime risk of surgery for either SUI or POP is 20%, and various publications report ranges from 30%-56% of all surgery for prolapse and urinary incontinence performed in the US is done for recurrent prolapse. Younger women (age <60) and women with advanced prolapse (grade 3

or 4) are more likely to experience recurrent prolapse after vaginal repair. The reported numbers are most likely underestimates of recurrence rates as many women who develop recurrent prolapse do not actually seek surgical repair for their recurrence. Additionally, often occult SUI can be uncovered after a prolapse repair is performed that was unknown because of the prolapse.

B. Pelvic Organ Prolapse — Treatment

Treatment options for pelvic organ prolapse are myriad and can consist of non-surgical, more conservative, non-invasive treatment, or may require surgery. Non-surgical options include physical therapy, behavior modification and/or use of a pessary. These non-surgical options can successfully address milder prolapse, and are ideal for patients who are poor surgical candidates or who elect to forego surgery.

Surgical treatment of pelvic organ prolapse has always been challenging, and as previously stated is often plagued by recurrence. For example Jacquetin and colleagues reported the relative anatomic cure rates of the Prolift vs. native tissue repair, demonstrating greater anatomic cure in mesh repairs over native tissue in all of the nine cases reported. (See Jacquetin 2013, Table 1cited later in this report.) Additionally, in their 2001 paper, Weber and colleagues reported a 70% failure rate with anterior colporrhaphy. (Weber, 2001)

For many years, the only surgical options for treating prolapse required abdominal surgery which, while more durable in some instances, is more invasive, associated with longer operative time and higher cost, and often results in long-term side effects, including scarring and its implications for chronic pelvic pain and pain with sex. While some of the risks associated with abdominal prolapse repair have been tempered by the development and ultimate use of laparoscopy, these risks and sequelae are still present. Surgical options have included anterior and posterior colporrhaphy, site-specific defect repair, biologic grafts and native tissue repair, sacrospinous ligament fixation and uterosacral ligament plication. If asked, I can explain how these procedures are performed, how physicians are trained to perform them, and can further explain how these surgical options evolved over time, largely due to the techniques developed by surgeons seeking to improve, where possible, the efficacy rates of existing surgical procedures, while minimizing inherent risks associated with those procedures. These techniques were developed largely by trial and error, but in attempting such innovations, the surgical practice of treating pelvic organ prolapse improved over time. It is through such surgeon innovation that synthetic mesh came to be used to improve the outcomes associated with traditional surgical treatments. In fact, the use of mesh- augmented prolapse repair developed, in large part, as a result of the significant failure rates with native tissue repairs.

Prior to the advent of pelvic mesh, synthetic, polypropylene mesh had been used for decades in various abdominal procedures. Some surgeons were using polypropylene mesh in pelvic surgery as early as the 1960's in an effort to improve the outcomes of such treatment. (Lane 1962) Permanent polypropylene sutures have been used safely in patients for many decades in all types of surgery with little or no reported complications such as degrading, particle loss, enhanced scarring, or increased infection rates.

Various mesh products have long been utilized to treat abdominal hernias, primarily to reduce the recurrence of hernias repaired by traditional non-mesh surgery. Polypropylene mesh is one type of mesh that came to be frequently used in repairing abdominal hernias. As word spread about the effectiveness of polypropylene mesh to treat hernias leading to less recurrence, pelvic surgeons took note and began incorporating such mesh in their surgical prolapse repairs. Initially, surgeons used mesh products that required them to manually cut or tailor the mesh at the time of surgery to adapt it to the individual patient's prolapse(s). These grafts were cut or tailored by the surgeon at the time of surgery, and could be cumbersome and difficult to safely attach to supportive structures like the sacrospinous ligament or to the arcus tendineus fascia. While many studies were undertaken to evaluate these new mesh-incorporating techniques, surgeons noted that data from such studies were inherently difficult to interpret due to the

variability of the techniques from surgeon to surgeon and lack of consistent mesh components fashioned by the surgeon.

D. Development Of and Experience with Gynemesh PS™, Prolift, Prolift +M and Prosima

1. Mesh utilized in various abdominal and pelvic surgery

In 1997, the Amid mesh classification was published classifying various hernia mesh primarily based on pore size and the relative pore size in relation to rates of infection and tissue integration. Given the classification's acceptance among physicians and scientists, it was applied to classification of pelvic mesh as well. This classification essentially categorized mesh as either macroporous (pore size of >75 μm), or microporous(< 75 μm). Macroporous is the preferred mesh in pelvic surgery because it allows passage of leukocytes and macrophages 9–20 μm in size into the pores of the mesh, an important factor in minimizing bacterial infiltration and, therefore, infection. Infection-causing bacteria are often very small (<1 micron in size) and can infiltrate small-pore mesh, but the macrophages and leukocytes necessary to fight off such bacteria cannot. Mesh pore size >75 μm, like that used in Gynemesh PS™, Prolift, Prolift +M, and Prosima, allows macrophages and leukocytes to infiltrate the mesh and minimize the risk of infection. Additionally, the larger pore allows for the patient's tissue to integrate into the interstices of the mesh thereby providing for better support, prohibiting

encapsulation. Type 1 mesh is a macroporous (pore size > 75 μm), monofilamentous polypropylene mesh which has been the standard mesh used in pelvic floor prolapse surgery. Gynemesh PS™ (Prolene Soft), the mesh used in the Prolift products and Prosima, is a type 1 mesh with a pore size of approximately 2.5 mm or 2,500 μm, and is the choice of mesh preferred by many pelvic floor surgeons for the treatment of both prolapse and stress urinary incontinence. The pore size of Prolift + M, which is composed of Gynemesh PS™ and monocryl (Ultrapro) is 3.5 mm post-absorption, thereby meeting the Amid classification as a monofilament lightweight Type 1 mesh.

Notably, the pore-size of Gynemesh PS™, Prolift (2.5mm) and Prolift +M (2.5-4.0mm) are significantly larger than 75 microns. I am aware of no reliable data, nor is it my experience, that the pores in the above meshes collapse once implanted. It is my opinion that the tissue integration with these products is sufficient to prevent pore collapse.

Types 2, 3, and 4 meshes such as Gore-Tex™ and Mersilene™, were formerly used in pelvic surgery; they are microporous (pore size < 75 μm), multifilament meshes which have largely been abandoned for use in transvaginal surgery as they were found to be prone to infection, associated with greater wound complications, and did not incorporate well into native tissue.

Type 1 mesh, like Gynemesh PS™, works with the body's host defense mechanisms promoting what is referred to as local inflammatory reaction and formation of fibrous tissue (like scarring); that inflammation often decreases with time. Chronic inflammatory cells commonly present in vaginal tissue are often observed near implanted mesh. This host defense mechanism is a normal foreign body response and is expected, a fact well-known to surgeons implanting foreign material, including pelvic mesh. Accordingly, the presence of chronic inflammatory cells reported in a pathology report evaluating explanted pelvic mesh of does not indicate an unexpected or abnormal finding, nor does it represent an adverse biologic reaction or defective mesh.

The types of mesh used in pelvic surgery evolved over time. The polypropylene mesh used for prolapse repair was initially Gynemesh which was significantly lighter than traditional abdominal hernia meshes. Gynemesh PS™, a second generation mesh, was lighter then Gynemesh, and improved elasticity as described by the original TVM group. (Berrocal J, et al. The TVM Group. Conceptual advances in the surgical management of genital prolapse, J Gynecol Obstet Biol Reprod 2004; 33:577-587.) Additional meshes were developed in this ever-evolving effort to provide safe and effective treatment options for pelvic floor disorders, including Ethicon- manufactured Vypro and Ultrapro, meshes commonly utilized in hernia surgery.

Vypro mesh (types I and II), comprised of polypropylene and polyglactin (PGA) has greater elasticity and larger pores, and was developed as a treatment for incisional hernias. While initial experimental and clinical studies of Vypro mesh were promising in the hernia context, studies of Vypro in the context of pelvic floor repair did not provide the same results. Lim and his colleagues reported that incorporating Vypro II as an overlay into a posterior colporrhaphy was associated with an unacceptably high incidence of complications. [Lim, Int Urogynecol 2007]. Jacquetin and his colleagues reported poor tolerance for the Vypro used to treat POP, as well as high rates of erosion and problems with cicatrisation, retraction and rigidity. Denis S, Pelvic Organ Prolapse Treatment by the vaginal route using a Vypro® composite mesh: Preliminary results about 106 cases. 2004 ICS IUGA. While limited in clinical use, Ultrapro showed some potential for reducing the inflammatory reaction in animal studies and was later used in Prolift +M, although later comparative studies showed that complications did not differ significantly from Prolift.

The advent of Prolift began in 2000 and was an attempt to make prolapse surgery with vaginal mesh easier and more standardized by using an ergonomically designed "kit". (Berrocal J, et al. The TVM Group. Conceptual advances in the surgical management of genital prolapse, J Gynecol Obstet Biol Reprod 2004; 33:577-587.) It was thought that such an ergonomic design should in theory

reduce human error, allowing for higher quality, reproducible results and less intraoperative risks.

2. Gynemesh PS™

Since approximately 2002, Ethicon has marketed Gynemesh PS™ in various size rectangular sheets for use in POP surgery, allowing for doctors to cut the mesh themselves depending on the type surgery they are performing and the size specific to their patient. When sold in this way, Gynemesh PS™ does not include any surgical tools, but rather is sold exclusively as a mesh product. It continues to be marketed today for abdominal use and is commonly used in abdominal sacral colpopexy procedures. In my opinion, based on the literature and medical information available to me, and my own experience, Gynemesh PS™ is not defective and provides a reasonably safe and effective option for treating pelvic floor disorders.

3. Prolift

In approximately 2003, a group of French physicians led by Dr. Jacquetin began to develop a surgical technique for transvaginal repairs of POP which ultimately evolved into the Prolift product. Rather than rectangular sheets of Prolene Soft (Gynemesh PS™) mesh, the Prolift provided a pre-shaped Gynemesh

PS™ mesh in a spider-type configuration, with arms/straps to be used to secure the mesh in a tension-free manner. The purpose was to provide a pre-cut shape of Gynemesh PS™ based on the shapes surgeons were previously cutting from larger rectangular sheets of mesh. Prolift was marketed in a kit that provided not only the mesh, but surgical tools to be used in implanting the mesh, including a guide, a cannula which fit over the guide, and a wire-like retrieval device which attached to the mesh and was pulled through the cannula to the exit point.

As described above, Prolift is comprised of the same mesh as Gynemesh PS™, and offers more comprehensive prolapse repair compared to traditional prolapse surgery, as a result of the "built in" lateral and distal fixation mechanisms or arms. The Prolift IFU and professional materials clearly describe how the mesh should be placed—flat and tension-free. These directions were provided to physicians, not only in the IFU's and professional materials provided by Ethicon, but also in the training sessions Ethicon made available to all physicians seeking to use its pelvic mesh products.

The delivery system, described above, allows easier access to the arcus tendineus, as well as the sacrospinous ligament, a structure that lies outside the abdominal cavity, thereby potentially decreasing the risk of vascular and visceral injury. Randomized controlled trials have compared the Prolift to traditional

sacrospinous ligament fixation. These trials demonstrated that the Prolift augmented procedures were more durable than the sacrospinous ligament fixation with no increase in blood loss or serious bleeding complications. (Halaska M, et al. A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of post-hysterectomy vaginal vault prolapse. Am J Obstet Gynecol. 2012 Oct; 207(4):301.e1-7; Svabik K, et al. Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. Ultrasound Obstet Gynecol. 2014 Apr; 43(4):365-71; da Silveira DRB, et al. Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. Int Urogynecol J. 2015 Mar; 26(3):335-42.) This use of mesh increased the durability of the repair because of its ability to address all levels of support defects. In addition to the fact that use of the Prolift system allowed for a surgery that is less invasive than the abdominal sacrocolpopexy (ASC), in many instances the Prolift procedure led to improved success over traditional vaginal prolapse repair, in a shorter period of time, using a standard, and therefore reproducible technique.

Moreover, the standardized approach allowed multi-center comparisons of surgical procedures and their respective outcomes that before were challenging and

difficult to do. As a result, the Prolift has been studied since 2005 with well over 100 studies having been published to date. Such studies were in some instances sponsored by Ethicon, and many were preformed independently of Ethicon. Whoever the sponsor, though, the results of these studies were published and presented to and analyzed by pelvic surgeons in their reviews of medical literature and at professional society meetings every year since it was launched. These peer-reviewed studies overwhelmingly demonstrate the consistent success of the Prolift at achieving long-lasting anatomic cure, and it is from these types of studies that surgeons obtain information about the frequency and severity of complications and how to manage those complications—NOT from a product IFU.

Interestingly, the traditional procedures utilized in surgically treating prolapse prior to the advent of the Prolift and other mesh devices, including native tissue repairs, were rarely analyzed in randomized controlled trials, even for surgeries that had been in existence for many decades. Yet, such procedures were performed safely, if not as effectively as the use of Prolift in some instances, and continue to be performed by some surgeons today. The quality of studies and medical research has significantly improved over the past two decades. Part of what has made that feasible is the ability to study a standardized procedure such as Prolift, which allows surgeons and researchers to compare results for consistency across the globe.

Randomized controlled, clinical trials (RCT's) comparing Prolift and Gynemesh PS™ to native tissue repair, have demonstrated high levels of patient satisfaction with significantly improved symptoms and quality of life, and importantly better anatomic cure. (Carey M, et al. Vaginal repair with mesh versus colporrhaphy for prolapse: a randomized controlled trial. BJOG 2009; 116(10):1380–1386; Withagen MI, et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. Obstet Gynecol 2011; 117(2 Pt 1):242–250(showed that complications decrease as surgeon experience increases); Altman D, et al. Nordic Transvaginal Mesh Group (2011) Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. N Engl J Med 2011 364(19):1826–1836 (cure rates were statistically significant, favoring Anterior Prolift, but dyspareunia rates were not statistically significant between Prolift and anterior colporrhaphy); Sokol AI, et al. One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. Am J Obstet Gynecol 2012; 206(1):86.e1–86.e9 (similar rate of mesh erosion/exposure as suture erosion/exposure (15%); Halaska 2012 (mesh exposures generally easily managed with conservative treatment); Svabik 2014; da Silveira 2014). Notably, sexual function (PISQ-12) improved and there were no statistically significant differences in new-onset dyspareunia, vaginal diameter, vaginal volume or total vaginal length for Prolift (9.1%) versus the no-mesh group

(21.4%) (P=0.60). Another important result of some studies showed that while the erosion rate for Prolift was15%, the no-mesh arm revealed a 15% suture erosion rate. (Sokol 2012)

Various RCT's and large meta-analysis have now demonstrated that vaginal mesh augmentation significantly decreases the risk of prolapse recurrence, particularly in anterior compartment prolapses. (Maher Cochrane Review 2013, Jacquetin B, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study. Int Urogynecol J. 2013 Oct; 24(10):1679-86; see Table 1 below).

Table 1 Randomised controlled trials comparing polypropylene mesh with traditional native vaginal tissue repairs

Reference	Total number patients	Follow up (months)	Compartment studied	Anatomic cure mesh (%)	Anatomic cure traditional (%)	*p*
Hiltunen et al. [9]	104	12	Anterior	93	62	<0.04
Sivaslioglu et al. [10]	90	12	Anterior	91	72	<0.05
Nieminen et al. [11]	105	24	Anterior	89	59	<0.05
Nguyen and Burchette [12]	75	12	Anterior	87	55	<0.05
Carey et al. [13]	139	12	Anterior Posterior	81	65.6	0.07
Nieminen et al. [14]	202	36	Anterior	87	59	<0.0001
Withagen et al. [15]	194	12	All	90	55	<0.001
Altman et al. [16]	389	12	Anterior	82	48	0.008
Sokol et al. [17]	65	12	All	38	30	0.45

Although mesh augmentation improves durability of prolapse repair, especially in the anterior compartment, as with all surgical treatments of prolapse, it is not without risks. The most common complication essentially unique to mesh augmentation is mesh exposure/erosion/extrusion. Studies have shown that with appropriate patient selection and with correct technique, this exposure risk can be

minimized (2%-9%). Moreover, successful treatment of exposure can be accomplished with the use of estrogen cream or in some instances with minimally invasive procedures to clip the areas of exposure. In some instances the exposure can resolve with no treatment. Often, the patient is not even aware of the exposure until told by their physicians after routine examinations.

Less common risks are mesh exposure/erosion/extrusion and contraction which require surgical correction. As with mesh exposure, instances of exposure/extrusion/erosion and contraction can be minimized with appropriate technique and patient selection. (de Landsheere L, et al. Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol. 2012 Jan;206(1):83.e1-7) As surgeons have more experience implanting mesh, instances of exposure/erosion/extrusion are much less, leading to the inescapable conclusion that many of the reports of mesh erosion/exposure/extrusion are due to technique than to any characteristic of the mesh. Importantly, mesh exposure is often the result of conditions like reduced estrogen, smoking, and poor wound healing due to conditions like diabetes, to name a few. In any event, surgeons have long understood that mesh exposure/erosion/extrusion occurs with devices such as the Prolift, as well as all other pelvic mesh devices. The medical literature is replete with discussions of exposure/erosion/extrusion risks associated with

mesh and has been for many years. Moreover, what is often referred to as mesh contraction is, in fact, contraction of tissue in which the mesh has been implanted as part of the healing process. Some people experience more contraction than others because of factors that are patient-specific. In my experience, the mesh does not contract; but tissue contraction and scarring can occur, just as with any type of surgery. Thus, a mesh erosion or exposure does not mean that there is a defect with the mesh. Regardless, mesh erosions and exposures are well-known and accepted complications with using mesh, and are commonly easily treated and resolved. Similarly, mesh erosion and exposures typically occur at the incision line and within the first post-operative year or two, most commonly attributed to poor wound healing and/or surgical technique.

No surgical option for treating pelvic organ prolapse is without risk. Abdominal surgery, in particular the ASC, is more morbid because entry into the abdominal cavity is a necessary part of the surgery, and has significant, in some instances life-threatening risks, including, among others: major vessel or visceral injury, sacral osteomyelitis, abdominal wound infection, abdominal hernia, risk of ileus and bowel obstruction, and significant adhesion formation.

Laparoscopic and robotic surgeries are associated with the same risks above, as well as risks associated with insufflation, steep Trendelenburg positioning, and trocar and instrument injury.

Any pelvic surgery carries with it a risk of post-surgery dyspareunia and chronic pelvic pain. Dyspareunia, with or without pelvic surgery is a very common complaint in women in general, as well as those with prolapse. It is a very difficult condition to treat in any instance, and is often multi-factorial, involving vaginal atrophy, decreased libido, partner issues and other causes, and often has a significant psychological component.

Notably, dyspareunia is associated with all prolapse surgeries, as are contraction, scarring and vaginal tightening/shortening—risks that are well-known. These risks are also associated with other types of gynecologic surgery such as hysterectomies. The pain/dyspareunia associated with pelvic floor surgeries can be transient or chronic. It has been reported that up to 64% of sexually active women attending urogynecology clinics suffer from female sexual dysfunction (Dietz V, Maher C. Pelvic organ prolapse and sexual function. Int Urogynecol J. 2013 Nov;24(11):1853-7.) Notably, these investigators' metanalysis showed that there was no difference in post-operative dyspareunia, de novo dyspareunia or PISQ-12 scores with Prolift use. In a study of 129 patients who had a baseline rate of 36.8%,

Lowman et. al. reported a 16.7% rate of de novo dyspareunia following Prolift use, and the rate reported by Lowman et.al. was consistent with the lower range of de novo dyspareunia seen with other prolapse surgeries:

TABLE 4
De novo dyspareunia after prolapse surgery

Dyspareunia	ASC N = 224 (148)[a] Handa et al[21]	SSLF N = 287 (106)[a] Maher et al[6]	USS N = 110 (34)[a] Silva et al[27]	APR N = 165 (81)[a] Weber et al[18]	Prolift N = 129 (57)[a]
Baseline (preop) dyspareunia (%)	40.5 (60/148)	Unknown	20.6 (7/34)	8.0 (6/81)	36.8 (21/57)
De novo (postop) dyspareunia (%)	14.5 (11/76)	36.1 (22/61)	25.9 (7/27)	19.0 (14/75)	16.7 (6/36)

[a] Number sexually active preop.

Lowman. Does the Prolift system cause dyspareunia? Am J Obstet Gynecol 2008.

Some longer term studies evaluating Prolift and Gynemesh PS™ have demonstrated good efficacy and subjective cure/quality of life improvements, a low rate of reoperation for prolapse, and acceptable rates of complications. (Benbouzid S, et al. Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow up. Int J Urol. 2012 Nov; 19(11):1010-6; de Landsheere L, et al. Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. Am J Obstet Gynecol. 2012 Jan; 206(1):83.e1-7; Miller D, et al. Prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse-5-year results. Female Pelvic Med Reconstr Surg. 2011 May; 17(3):139-43; Jacquetin B, et al. Total

transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study. Int Urogynecol J. 2013 Oct;24(10):1679-86.)

Recently, studies comparing Prolift and native tissue repair show no overall difference in de novo dyspareunia, de novo pelvic pain, sexual functioning by PISQ scores, change in total vaginal length, and change in vaginal diameter and volume (Carey 2007; Withagen 2011; Altman 2011; Sokol 2012; Halaska 2012; Svabik 2014; da Silveira 2014). While there are high levels of preexisting dyspareunia and sexual dysfunction in women suffering from prolapse, Prolift appears to have an overall positive effect on dyspareunia rates and sexual function. These findings are consistent with my experience.

4. Prolift +M

Although the Gynemesh PS™ and Gynemesh-containing devices like Prolift, were completely safe and effective for use in pelvic surgery, efforts to further develop and refine pelvic mesh were undertaken in order to continually add to and improve a physician's surgical options, as has been the case for many products and procedures used in treatment of pelvic floor disorders. As discussed above, risks inherent in utilizing synthetic mesh included tissue contraction, exposure/erosion or extrusion, foreign body reaction that occurs with any graft material, and dyspareunia—all of which were well-known to surgeons. Nevertheless, studies of partially absorbable mesh were initiated in an attempt to

minimize or at least reduce these risks. [Ozog Int Urogynecol 2012]. Ethicon's Prolift + M was one of the products developed as part of this effort.

Prolift +M differs from Prolift in that it is composed of Ultrapro, a blend of 50% absorbable polyglecaprone 25 (which is the product used in Monocryl, an absorbable suture) knitted with 50% monofilament nonabsorbable polypropylene. It is a lighter weight mesh once the absorbable mesh is absorbed. This materials change allowed increased elasticity with the hope of reducing dyspareunia.

Studies were published attesting to the safety and efficacy of Prolift +M. Milani and her colleagues published the results of their prospective, multicenter study evaluating anatomic and functional outcomes with Prolift +M. At one year there were significant improvements noted in quality of life and dyspareunia when compared to baseline. They reported 86.2% of patients reported prolapse to be improved; 10.2% exposures; and 2% de novo dyspareunia—all risks which are low compared to native tissue repairs. In a study by Ozog and his colleagues, Prolift +M implants were noted to shrink by only 4.3% without significant differences between the two directions of implantation [Ozog Y, Konstantinovic ML, Werbrouck E, De Ridder D, MazzaE, Deprest J (2011).

While the biomechanical properties of Prolift +M were attractive in theory, Prolift +M did not provide long-term clinical superiority to Prolift. Numerous

studies were conducted comparing Prolift +M to other types of prolapse surgery, including devices utilizing Prolift-type meshes. They found that absorbable mesh did not provide advantages over the Prolift-type mesh (non-absorbable mesh) when analyzed for rates of re-operation. *See* Elmer C. et.al, Trocar-guided transvaginal mesh repair of pelvic organ prolapse. Obstet Gynecol (2009); Milani A. et.al. A light-weight mesh system for trans-vaginal prolapse repair: interim 3 months result 1057 Prolift +M Congress Poster (2009); Milani, A. et.al. Trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh: 1 year outcomes (Obstet Gynecol 2011); Milani A. Medium-term clinical outcomes following trocar-guided mesh repair of vaginal prolapse using partially absorbable mesh. Int Urogynecol J (2012); Khandwala Int Urogynecol (2011); de Landsheere et al., Am. J. Obstetrics and Gynecology (2012); Benbouzid S, Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow up, Int. J Urology (2012); Moore R, Comparison of vaginal mesh extrusion rates between a lightweight type I polypropolene mesh versus heavier mesh in the treatment of pelvic organ prolapse, Int Urogynecol J (2012); Bhatia N, A, Comparison of sexual function outcomes procedure using polypropylene mesh vs. hybrid polypropylene/poliglecaprone mesh (2012); Lensen E, Comparison of Two trocar-guided trans-vaginal mesh systems for repair of pelvic organ prolapse; a

retrospective cohort study, Int Urogynecol J (2013); Quemener J, Rate of re-interventions after transvaginal pelvic organ prolapse repair using partially absorbable mesh: 20 months median follow-up outcomes, Eur J obstet Gynecol (2014). These studies demonstrated that Prolift and Prolift +M provided essentially equal efficacy, risks and benefits.

A review of the data, cited above, demonstrates clearly that neither the Prolift +M, nor the Ultrapro mesh used in the Prolift +M, is a safer or more effective device or alternative treatment for POP. Rather, like Prolift and Prosima, Prolift +M was simply an additional tool in the physicians' armamentarium for treating POP, to be used based on the surgeon's preference, skill, training, experience and comfort in using the specific product, as well as and his/her own judgment considering the individual patient's characteristics and needs.

While I elected to use Prolift +M after it was introduced to the market, my election was based on personal preference. Were it still marketed in the United States currently, I would still employ it in treating POP.

5. Prosima

In 2010, Ehicon began marketing the Prosima device to provide yet another surgical option for treating POP. The Prolift and Prolift + M required advanced surgical skills, and Ethicon wanted another option for physicians who might not have been as comfortable using the earlier devices, but which provided a safe and

effective option/alternative for treating POP's.

The mesh component of Prosima is Prolene Soft mesh, which is the same mesh as the Gynemesh PS™ mesh used in Prolift. However, the two kits are different. First, Prosima's mesh component is smaller than the Prolift; instead of a spider shape, as in Prolift, the Prosima mesh is somewhat triangular, and does not have mesh straps. The kit does not use trocars (the guide and cannula used in Prolift) to deliver the mesh through exit points in the upper thigh. Rather, a "vaginal support device" (VSD) with an inflatable balloon is inserted into the vagina to keep the mesh in place initially after surgery to allow for tissue ingrowth into the mesh implant. The balloon is inflated at the close of the implant surgery and placed in the vagina (replacing the usual gauze packing) and is removed the day after surgery. The VSD then remains in place for up to 28 days post-surgery. Prosima requires less dissection than other kits; avoids deep passes; and does not exit the pelvic cavity into the thighs. Like Prolift, though, Prosima provides Arcus to Arcus support, and supports the vagina through tissue in-growth.

Prosima has been well-studied, particularly given the short period it was marketed. The published data on Prosima demonstrates that it is a safe and effective treatment for prolapse. *See* Sayer T, et.al. Medium-term clinical outcomes following surgical repair for vaginal prolapse with tension-free mesh and

vaginal support device. Int Urogynecol J (2012); Zyczynski H, et.al., One-year clinical outcomes after prolapse surgery with non-anchored mesh and vaginal support device, Am J Obstet Gynecol (2010); Bezenar V, et. al. ICS Abst. 765 The pelvic floor repair with the use of Prosima implant—the assessment of complications and life quality (2013); Carey M et.al. Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device, BJOG (2008).

Prolift, Prolift +M and Prosima have been demonstrated to be safe and effective in treating POP, and they were important options for surgeons treating pelvic floor disorders. In my opinion that, and based on my own experience, Ethicon's products for treating POP are superior to other devices. The number of complications I have treated are significantly less with the Ethicon POP products.

6. Claims of Degrading, Particle Loss, Roping, Fraying, Curling and Cytotoxicity

It is my understanding that litigation-related claims have been made that polypropylene mesh such as that used in the Prolift, Prolift +M and Prosima is carcinogenic, degrades in situ, contracts, results in particle loss, all of which factors have clinical implications, including scarring, chronic pain and inflammation and increased infections. I am aware of no clinical data

demonstrating that such conditions occur, and certainly there is no accepted, reliable data suggesting that even if such conditions exist, they have any clinical significance whatsoever. Given the number of patients in which polypropylene mesh has been implanted, including Gynemesh PS™, the Prolift line of products Prosima, and the various mid-urethral slings like the TVT line of products, as well as the hundreds of studies and analyses and trials evaluating such pelvic mesh products, if any such conditions were occurring with any frequency and clinical significance, one would certainly expect published reports to exist. They do not.

Additionally, the most prestigious and respected professional organizations which govern the standards of gynecologic and urologic treatment of pelvic floor dysfunction, including the American Urogynecologic Society (AUGS), the American Urologic Association (AUA), the International Urogynecologic Association (IUGA) and the American College of Obstetricians and Gynecologists (ACOG) in 2015 all acknowledge that there is a role for vaginal mesh augmentation in treatment of pelvic floor dysfunction. See citations to these publications in Exhibit A.

Importantly, if there were any reliable data demonstrating or even suggesting that the use of polypropylene mesh in treating pelvic floor dysfunction increases the risk of cancer, or causes permanent malady through particle loss, degradation,

roping, fraying, and curling, as claimed, these organizations would hardly make such statements and recommendations they have published. Assertions that these devices were "unreasonably dangerous" or "defective" as I understand are being alleged by some plaintiffs' witnesses, are completely inconsistent with the position statements of these societies, but also with the voluminous published data relating to polypropylene pelvic mesh and my clinical experience. While pelvic mesh may not be the preferred choice for certain surgeons or patients, it does serve as an important option for treating prolapse, especially in patients with more severe prolapse or patients who have undergone a previously failed native tissue procedure.

Overall, the evidence supports the use of vaginal mesh augmentation to decrease recurrence risk in patients, particularly for those in whom abdominal or lengthy surgery may be unnecessarily risky (obesity, multiple prior abdominal surgeries, medical co-morbidities, advanced age, etc.). The benefits of mesh outweigh the risks. Most transvaginal mesh complications can be minimized with proper technique and appropriate patient selection. Polypropylene mesh devices, and specifically the Prolift device, are an important surgical option in the treatment armamentarium for pelvic organ prolapse repair. Not having that option available, in my opinion, has negatively and significantly affected my ability to offer a

minimally invasive, safe and effective treatment to appropriate patients who could benefit from its use.

B. Information Provided to Physicians

While Ethicon made available to surgeons IFUs, patient brochures, a Surgeon's Resource Monograph, a technical guide and made training sessions for the use of its devices, including the Prolift, Prosima, and Prolift +M, available to surgeons, it is my opinion, as a pelvic floor reconstructive surgeon, that while those materials are important, neither I nor my colleagues, nor any surgeon that I know of or have trained, rely on IFU's or instructions from device manufacturers as our primary means of learning about the products used in surgery, the methods of using or implanting surgical prosthetics, or risks associated with their use. Rather, we learn how to perform any surgery, including prolapse surgery utilizing pelvic mesh, in residency, fellowship and by proctorship. It is my experience that many surgeons never read the IFU, or other materials provided by manufacturers. As practicing physicians, we have little or no time to meet with manufacturers' representatives, and given the number of prescription products and devices we either prescribe or utilize on a regular basis, we neither expect nor rely on pharmaceutical companies to provide us with our primary means of understanding the risks associated with products they sell. Rather, we rely on published medical

articles, presentations at professional meetings, and discussions with colleagues. We rely on evidence-based medicine and our own experience to dictate our treatment choices.

The original Prolift, Prosima, and Prolift +M IFUs warned of several risks including, but not only, damage to nerves, vessels, bladder and bowel, inflammation, adhesions, erosion, extrusion and scarring that results in implant contraction. Any surgeon practicing pelvic reconstructive surgery understands that these complications may cause pain and dyspareunia, as well as the need for additional surgery.

I have reviewed the professional education materials offered to surgeons by Ethicon relating to their pelvic mesh products, and it is my opinion that Ethicon adequately apprised physicians practicing pelvic reconstructive surgery of the risks associated with the use of Gynemesh PS™, Prolift, Prosima and Prolift +M, and that risks associated with the these products were adequately described in their respective IFUs and other professional education materials.

The professional education materials and 2007 Prolift surgeon monograph, which supplement the IFUs, warn of complications like contraction, erosion, pain and dyspareunia and discuss management of these complications. The Patient Brochures available for dissemination by physicians as a supplement to a

physicians' specific discussions of the product with their patients were never intended to supplant the discussion by the doctor. Nevertheless, they provided adequate information to lay persons to supplement discussions with their physicians regarding treatment options for prolapse repair.

Ethicon's professional education materials and training were most helpful in informing physicians of the proper use and risks associated with its product. While in my opinion it is not a device manufacturer's responsibility to train surgeons, such training is a valuable service to physicians and offers them not only the opportunity to continue their medical education and knowledge, but provides access to other and in some instances, more experienced surgeons, and provides them with the opportunity to improve their surgical skills. The instructions and professional materials provided by Ethicon, make clear that their mesh products should be used by experienced physicians. The training and other educational opportunities provided by Ethicon allow surgeons to gain knowledge and experience regarding Ethicon's products. Professional education offered by Ethicon has been more than adequate, and in fact exceptional, in my opinion. In my opinion, Ethicon was very responsible and thorough in the way they studied their products and trained physicians in how to use them.

The opinions reflected in this report are based on information currently available to me. I reserve the right to modify or amend these opinions as new information becomes available.

E. Stanton Shoemaker, M.D.